Remarks

It is requested that the foregoing amendment be entered and that the rejections be reconsidered. Claims 1-3, 6-13, 65-68, and 73-74 were examined in this case. Claims 1-3, 6-13, 65-68, and 73-74 stand rejected under 35 U.S.C. § 112, second paragraph, and 35 U.S.C. § 102. In this response, claims 1 and 6 have been amended to more particularly point out and distinctly claim the invention. Applicant submits that this amendment does not present any new matter. Applicant additionally respectfully submits that in view of the arguments presented below, the claims are now in condition for allowance.

Rejection under 35 U.S.C. § 112, second paragraph:

The Examiner has rejected claim 6 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner states that the term "biomolecular interaction" is vague and indefinite and asserts that Applicant's argument (paper no. 15, page 6) is not persuasive because no definition of the term is seen in any of the cited locations in the specification. In order to expedite allowance of the claims, the term "biomolecular interaction" has been deleted from claim 6 and replaced with the term "anchor-adapter-tag unit," which is clearly defined in the application at page 2, lines 15-19. In light of the amendment to claim 6, withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. § 102(b):

Claims 1-3, 6-13, 65-68, 73 and 74 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hoffman et al. (Artificial Organs 16:43 1992)). The Examiner asserts that Hoffman discloses materials for use in tissue engineering that meet all of the limitations of each of the claims (e.g., nucleic acids and antibodies (pages 44-45)). Applicant disagrees with this rejection.

Independent claim 1 is directed to a composition comprising a biodegradable polymer having a ligand attached thereto, wherein said ligand is attached to said biodegradable polymer using an anchor-adapter-tag-unit, wherein the adapter interacts with an anchor and a tag simultaneously, wherein the anchor interacts with the polymer and the tag interacts with the ligand. Independent claim 2 is directed to a composition comprising a biomaterial architecture

having a ligand attached thereto through a biomolecular interaction, wherein said biomaterial architecture comprises a polymer having an anchor moiety incorporated therein or attached thereto, and wherein said biomolecular interaction further comprises an anchor-adapter-tag unit, whereby the tag is attached to the ligand, and wherein said adapter is bound to both the anchor and the tag to effect the biomolecular interaction.

As set forth in the claims, the inventive composition includes an anchor-adapter-tag unit that links a biodegradable polymer to a ligand. The inventive composition includes *three* components: 1) an anchor; 2) an adapter; and 3) a tag, which are attached in that order [anchor-adapter-tag] and used to link a ligand to a biodegradable polymer. Neither the ligand nor the polymer is one of the three components of the anchor-adapter-tag unit. As set forth in the claims, the anchor interacts with the polymer, the tag interacts with the ligand, and the adapter interacts with both the anchor and the tag *simultaneously* forming the three-component anchor-adapter-tag unit (see also page 2, lines 16-20 and page 7, lines 8-11).

The specification describes one anchor-adapter-tag unit, wherein the anchor is biotin, the adapter is avidin or streptavidin, and the tag is biotin (e.g., polymer-[biotin-(avidin or streptavidin)-biotin]-ligand) (see page 7, lines 12-13). The specification also teaches that "a hapten may be used as the anchor and the same or a different hapten used as the tag, with an antibody of the requisite specificity/specificities used as the adapter" (e.g., polymer-[hapten1-antibody-hapten2]-ligand) (page 7, lines 17-19). In yet another example, the specification teaches that an antibody fragment may also be used as an anchor or a tag molecule and the adapter molecule comprises epitopes for the anchor and/or tag, as appropriate (e.g., polymer-[antibody1-epitope-antibody2]-ligand) (see page 7, lines 19-20). Thus, the claimed composition clearly includes three components that form an anchor-adapter-tag unit that links a polymer to a ligand.

Nowhere does Hoffman et al. disclose a composition including three components equivalent to an anchor, an adapter, and a tag that link a polymer to a ligand. What Hoffman et al. do teach is that biological functions may be incorporated onto biomaterial systems by immobilizing the biofunctional on soluble polymer backbones (page 44, columns 1-2). Hoffman states that Figure 1 shows "an example of the wide range of biologic functions that could be built into a soluble polymer molecule" (see page 44, column 2 and Figure 1). The biologic functions

shown in Figure 1 (ligand; signal group; lipophilic group; plasmid vector; non-functional group) are illustrated as being attached to a polymer and consist of only *one* component (not three).

One biologic function provided in Figure 1 that could be considered to have at most two components is the "Biofunctional molecule (*linked by biodegradable spacer arm*). The two components include 1) the biofunctional molecule and 2) the spacer arm. Another system described in the Hoffman et al. reference that could be considered to include two components is the system that includes drugs conjugated to polymers, which are further conjugated with antibodies for targeted drug delivery systems (see page 45, column 1). The two components here are 1) the drugs and 2) the antibodies. No third component is included in either of these systems. Furthermore, in the drug/antibody system, both the drugs and the antibodies are conjugated to the polymer. In contrast, as set forth in the claims, only the anchor of the anchor-adapter-tag unit claimed interacts with the polymer.

That the Hoffman et al. reference describes systems with at most two components is further illustrated in Figure 2, wherein a cell is attached to a polymer. The components used to attach the cell to the polymer include 1) a cell adhesion peptide and 2) a biological recognition group that is immobilized on the surface of the polymer and interacts with the cell adhesion peptide (see legend of Figure 2). The systems illustrated in Figure 2 clearly lack a third component, which is integral to the claimed anchor-adapter-tag unit.

The Examiner has yet to identify three components in the Hoffman et al. system that link a polymer to a ligand. In fact, even the Examiner describes the Hoffman system as a two-component system. On page 2 of the final Office Action, the Examiner states, "For example, immobilized nucleic acids used in a binding assay are bound to an *anchor* and have an *adaptor* function in regard to the nucleic acids that bind to (see page 44 of the reference)." In the above statement, the Examiner fails to identify a third tag component. It appears that the Examiner cannot define three components of the Hoffman system because three components do not exist.

Anticipation under 35 U.S.C. 102 requires that the invention disclosed by the prior art reference must be identical to the claimed invention in each and every aspect. As stated in *Hybritech Inc. v. Monoclonal Antibodies, Inc,* 802 F.2d 1367,231 U.S.P.Q. 81 (Fed. Cir. 1986), "[I]t is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention." Nowhere do Hoffman et al. teach of a three-component anchor-adapter-tag unit for the purpose of adhering a ligand to the surface of a biodegradable polymer. Since the

claimed invention requires a three-component anchor-adapter-tag unit, the Hoffman et al. reference does not anticipate the claimed invention.

In light of the above arguments, Applicant submits that Hoffman et al. does not contain every element of the claimed invention, and thus is not anticipatory under 35 U.S.C. § 102(b). Applicant respectfully requests withdrawal of this rejection.

Conclusion

Based on the arguments presented above, it is submitted that the pending claims, as amended herein, are allowable over the art of record. Applicant would like to thank the Examiner for thoughtful comments and careful consideration of the case. If a telephone conversation would help expedite prosecution of this case, please do not hesitate to contact the undersigned at (617) 248-5216.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Please charge any fees that may be required, or credit any overpayment, to our Deposit Account No. 03-1721.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner For Patents, Washington, D.C. 20231
on May 23, 2002
Kathy Hart Gagnon

Version With Markings to Show Changes Made

In the Claims:

Claims 1 and 6 have been amended as follows.

1. (Twice Amended) A composition comprising a biodegradable polymer having a ligand attached thereto, wherein said ligand is attached to said biodegradable polymer using an anchor-adapter-tag-unit, wherein the adapter interacts with an anchor and a tag simultaneously, wherein the anchor interacts with the polymer and the tag interacts with the ligand.

6. (Thrice Amended) The composition of claim 2, wherein the anchor is capable of being incorporated into the polymer from which the biomaterial architecture is formulated, the tag is capable of attachment to the ligand, and wherein the adapter is capable of binding to both the anchor and tag moieties to generate an anchor-adapter-tag unit [a biomolecular interaction].